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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,432	03/31/2004	Thomas E. Wagner	035879-0182	3800

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,432	WAGNER ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *5-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/31/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on August 17/2006 in response to the Restriction Requirement of July 21, 2006 has been entered. Applicant's election of Group I, claims 1-4 and 10-18, as specifically drawn to a pharmaceutical composition comprising: (a) a carrier portion; (b) a targeting portion, wherein the targeting portion comprises a targeting peptide; and (c) an immune response triggering portion which triggers a complement mediated hyperacute immune response has been entered.

Applicant's election of Group I with traverse is acknowledged. The traversal is on the grounds that the claims of the remaining group are sufficiently related to the elected invention of Group I and therefore, such examination would not place an undue burden on the Examiner. For example, Applicants submit that MPEP 803 states that, if " the search an examination of an entire application can be made without serious burden, [then] the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." Therefore, Applicants assert that the Examiner should reconsider the restriction requirement and examine the claims of Groups I-II as one invention.

These arguments have been carefully considered, but are not found persuasive.

Regarding Applicants assertion that the examination of Groups I and II together would not place an undue burden on the Examiner, the Examiner recognizes that the inventions are classified differently. As such, the examination of Groups I and II together would necessitate different searches of the US Patents. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group. Moreover, as stated in the Restriction Requirement (page 2), a pharmaceutical composition (Group I) may be known even if the method of selectively inducing a complement mediated hyperacute immune response is novel.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-18 are pending.

Claims 5-9 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1-4 and 10-18 are currently under consideration.

Species Election

Applicant's election of "inhibitor" as the species from claim 13 is acknowledged.

Information Disclosure Statement

The Information Disclosure Statements filed on 9/15/2004 and 1/25/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDSs are attached hereto.

Drawings

Figure 1 is objected to because it is unclear what the "lines" represent. For example, the specification (page 5, paragraph 0011) teaches that Figure 1 shows that HAS-gal successfully competed with HAS-FITC, indicating that the sugar group incorporation onto HAS does not interfere with its antibody binding. However, Figure 1 does not appear to provide a means for determining one line from another. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-4 are inclusive of a pharmaceutical composition comprising a genus of targeting peptides and a genus of compounds which triggers a complement mediated hyperacute immune response. Moreover, Claims 10-17 are inclusive of a kit comprising a pharmaceutical composition comprising a genus of targeting molecules and a genus of compounds which triggers a complement mediated hyperacute immune response, wherein the targeting molecules are further limited to a genus of inhibitors and a genus of targeting peptides. Thus, the claims encompass a genus of molecules defined solely by its principal biological property, e.g., a targeting peptide, an inhibitor and an immune response triggering portion, which is simply a wish to know the identity of any material with that biological property. However, the written description in this case only appears to reasonably convey a pharmaceutical composition comprising a targeting peptide which comprises the tri-peptide motif of asparagine-glycine-arginine (NRG motif) or those found in US patent Nos: 6,528,481; 6,491,894, 6,296,832; and 6,180,084, one species of inhibitor, e.g., sodium 1-(12-hydroxy)octadecanyl sulfate, and one species of an immune response triggering portion, wherein the triggering portion is galactose-α-1,3-galactose.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

With regards to the targeting peptide, the specification teaches (page 6, paragraph 0019) that specific targeting peptides of the invention include, but are not limited to, inhibitors, ligands,

agonists, antagonists and substrates. The specification further teaches (page 6, paragraph 0019 and 0021) that the targeting peptides of invention may comprise a tri-peptide motif such as asparagine-glycine-arginine (NRG motif) or may not comprise a tri peptide motif such as those described in US Patent Nos: 6,528,481; 6,491,894, 6,296,832; and 6,180,084. With regards to the triggering portion, the specification teaches (page 8, paragraph 0027) that the triggering portion of the pharmaceutical composition of the preferred embodiment of the present invention is galactose-a-1,3-galactose. Thus, while the specification contemplates a targeting peptide being a ligand, an antagonist, an agonist, a substrate or an inhibitor, the specification only reasonably conveys a pharmaceutical composition comprising a targeting peptide which comprises the tri-peptide motif of asparagine-glycine-arginine (NRG motif) or those found in US patent Nos: 6,528,481; 6,491,894, 6,296,832; and 6,180,084, one species of inhibitor, e.g., sodium 1-(12-hydroxy)octadecanyl sulfate, and one species of an immune response triggering portion, wherein the triggering portion is galactose-α-1,3-galactose. Accordingly, there is insufficient written description encompassing a the genus of targeting peptides, inhibitors and triggering portion because the relevant identifying characteristics of the genus such as structure or other physical and/or chemical characteristics are not set forth in the specification as-filed, and therefore, is not commensurate in scope with the claimed invention. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed

correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of compounds that encompass the genus of targeting peptides and/or inhibitors nor does it provide a description of structural features that are common to the genus. Further, the specification fails to provide a representative number of compounds that encompass the genus of immune response triggering portions along with a description of structural features that are common to the genus. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a pharmaceutical composition comprising a targeting peptide which comprises the tri-peptide motif of asparagine-glycine-arginine (NRG motif) or those found in US patent Nos: 6,528,481; 6,491,894, 6,296,832; and 6,180,084, one species of inhibitor, e.g., sodium 1-(12-hydroxy)octadecanyl sulfate, and one species of an immune response triggering portion, wherein the triggering portion is galactose-α-1,3-galactose, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Corti (WO 01/61017 A2, 2001, IDS) as evidenced by Yang et al. (J. Exp. Med. 1998; 188: 247-254).

Corti teaches a pharmaceutical composition comprising a carrier portion, a targeting portion and an immune response triggering portion, wherein the carrier portion is human serum albumin, the targeting portion is a peptide comprising a NGR motif, and the immune response triggering portion is TNF (page 6, line 27 to page 7, line 7 and page 15, lines1-10). Thus, while Corti does not specifically teach that TNF triggers a complement mediated hyperacute immune response, the claimed limitation appears to be an inherent property of TNF because as evidenced by Yang et al., TNF is one of the major players in hyperacute responses triggering a cascade of immune responses (page 252, 2nd column, 1st full paragraph). Thus, the claimed product appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by

the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corti (WO 01/61017, 2001, IDS) in view of Patierno et al. (US 6,288,039, 2001).

Corti teaches, as applied to claims 1-3 above, a pharmaceutical composition comprising a carrier portion, a targeting portion and an immune response triggering portion, wherein the carrier portion is human serum albumin, the targeting portion is a peptide comprising a NGR motif, and the cytokine, TNF, as the immune response triggering portion (page 6, line 27 to page 7, line 7 and page 15, lines1-10).

Corti does not explicitly teach a kit comprising, in a suitable container, a pharmaceutical composition comprising a carrier portion, a targeting portion and an immune response triggering portion.

Patierno et al. teach pharmaceutical compositions and kits for treating and diagnosing breast cancer (abstract). Specifically, the reference teaches a kit for treating breast cancer comprising a therapeutically effective amount of an inhibitor in a pharmaceutically acceptable carrier and a device

for delivering the inhibitor to the breast cancer, wherein the carrier and device are packaged in a container (column 7, liens 61-67).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the pharmaceutical composition as taught by Corti as a kit in view of the Patierno et al.. One would have been motivated to do so because standard kits enhance the probability of the reproducibility and efficiency of the treatment process and further provide for increased marketability, convenience, reliability, and economy. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by packaging the pharmaceutical composition taught by Corti as a kit, one would achieve a convenient and reliable kit for use in the treatment of cancer.

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terman (US 6,340,461 B1, Jan. 22, 2002) in view of Ruoslahti et al. (US 6,180,084, 2001, IDS).

Terman teaches a pharmaceutical composition comprising a carrier, a superantigen and an immunotherapeutic antigen (column 15, line 40 to column 16, line 4). With regards to the immunotherapeutic antigen, the patent teaches (column 8, lines 1-12 and column 50, lines 10-14) that the immunotherapeutic antigens include, but are not limited to, galactose-1-3-galactose which elicits an acute-phase hyperimmune response. The patent further teaches (column 50, lines 48-54) that the immunotherapeutic antigen, e.g., galactose-1,3-galactose, can be modified with a monoclonal antibody to generate an antigen-antibody conjugate which specifically targets the cell surface of tumor cells.

Terman does not explicitly teach that the immunotherapeutic antigen can comprises a targeting peptide, wherein the targeting peptide comprises asparagine-glycine-arginine (NGR).

Rouslahti et al. teach tumor homing molecules comprising an NGR peptide motif, as well as NGR peptide conjugates (column 3, lines 1-10). Specifically, Rouslahti et al. teach that the NGR peptide targeted conjugates are advantageous over monoclonal antibody directed targeting because the NGR peptides target the vasculature of tumors, thereby reducing the likelihood that the targeted agent will kill sensitive normal tissues (column 1, liens 60 to column 2, lines 24).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute an NGR targeting peptide for the monoclonal antibody taught by

Terman in view of Rouslahti et al. One would have been motivated to do so because Rouslahti et al. teach that the NGR peptide targeted conjugates are advantageous over monoclonal antibody directed targeting because the NGR peptides target the vasculature of tumor, thereby reducing the likelihood that the targeted agent will kill sensitive normal tissues. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by administering to a patient a pharmaceutical composition comprising a NGR peptide and an immunotherapeutic antigen such as galactose-a-1,3-glalactose, one would achieve a pharmaceutical composition which targets the tumor vasculature and not the tumor cell surface.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terman (US 6,340,461 B1, Jan. 22, 2002) in view of Ruoslahti et al. (US 6,180,084, 2001, IDS) and in further view of Corti (WO 01/61017, 2001, IDS).

Terman in view of Rouslahti et al. teach, as applied to claims 1 and 3-4 above, a pharmaceutical composition comprising a carrier an immunotherapeutic antigen and a targeting peptide, wherein the immunotherapeutic antigen is galactose-1,3-galactose and the targeting peptide is a peptide comprising a NGR peptide motif. With regards to the carrier, Terman et al. teach that the carriers include, but are not limited to, serum albumin (column 15, lines 25-31).

Terman in view of Rouslahti et al. do not explicitly teach that the serum albumin carrier is human serum albumin.

Corti teaches a pharmaceutical composition comprising a carrier portion, a targeting portion and an immune response triggering portion, wherein the carrier portion is human serum albumin, the targeting portion is a peptide comprising a NGR motif, and the immune response triggering portion is TNF (page 6, line 27 to page 7, line 7 and page 15, lines1-10). Specifically, Corti teaches that the anti-tumor activity was not changed by the addition of human serum albumin to TNF and NGR-TNF solutions, as the carrier (page 15, lines 1-3)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use human serum albumin as the carrier in the composition taught by Terman and Rouslahti et al. in view of Corti. One would have been motivated to do so because Corti teaches that the anti-tumor activity of TNF was not changed by the addition of human serum as the carrier. Thus, one of ordinary skill in the art would have a reasonable expectation of success

that by using human serum albumin as the carrier for a pharmaceutical composition comprising a NGR peptide and an immunotherapeutic antigen such as galactose-a-1,3-glalactose, one would not change the anti-tumor activity of the pharmaceutical composition.

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terman (US 6,340,461 B1, Jan. 22, 2002) in view of Ruoslahti et al. (US 6,180,084, 2001, IDS) and in further view of Patierno et al. (US 6,288,039).

Terman in view of Rouslahti et al. teach, as applied to claims 1 and 3-4 above, a pharmaceutical composition comprising a carrier an immunotherapeutic antigen and a targeting peptide, wherein the immunotherapeutic antigen is galactose-1,3-galactose and the targeting peptide is a peptide comprising a NGR peptide motif. With regards to the NGR peptide motif, Rouslahti et al. teach that the NGR peptide motif specifically homes in vivo to breast tumor, melanoma, as well as, Kaposi's sarcoma (column 17, line 65 to column 18, line 2). In addition to the NGR peptides, Rouslahti et al. teach that aminopeptidase inhibitors such as bestatin can be used for directing a moiety to the angiogenic vasculature of a tumor (column 3, lines 5-10).

Terman in view of Rouslahti et al. do not explicitly teach a kit comprising, in a suitable container, a pharmaceutical composition comprising a carrier portion, a targeting portion and an immune response triggering portion.

Patierno et al. teach pharmaceutical compositions and kits for treating and diagnosing breast cancer (abstract). Specifically, the reference teaches a kit for treating breast cancer comprising a therapeutically effective amount of an inhibitor in a pharmaceutically acceptable carrier and a device for delivering the inhibitor to the breast cancer, wherein the carrier and device are packaged in a container (column 7, liens 61-67).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the pharmaceutical composition as taught by Terman and Rouslahti et al. as a kit in view of the Patierno et al.. One would have been motivated to do so because standard kits enhance the probability of the reproducibility and efficiency of the treatment process and further provide for increased marketability, convenience, reliability, and economy. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by packaging the

pharmaceutical composition taught by Terman and Rouslahti et al. as a kit, one would a convenient and reliable kit which can be used for the treatment of breast cancer.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terman (US 6,340,461 B1, Jan. 22, 2002) in view of Ruoslahti et al. (US 6,180,084, 2001, IDS) and Patierno et al. (US 6,288,039) and in further view of Corti (WO 01/61017, 2001, IDS).

Terman in view of Rouslahti et al. and Patierno et al. teach, as applied to claims 10-17 above, a kit in a suitable container comprising a pharmaceutical composition comprising a carrier an immunotherapeutic antigen and a targeting peptide, wherein the immunotherapeutic antigen is galactose-1,3-galactose and the targeting peptide is a peptide comprising a NGR peptide motif. With regards to the carrier, Terman et al. teach that the carriers include, but are not limited to, serum albumin (column 15, lines 25-31).

Terman in view of Rouslahti et al. and Patierno et al. do not explicitly teach that the kit comprises human serum albumin as the carrier.

Corti teaches a pharmaceutical composition comprising a carrier portion, a targeting portion and an immune response triggering portion, wherein the carrier portion is human serum albumin, the targeting portion is a peptide comprising a NGR motif, and the immune response triggering portion is TNF (page 6, line 27 to page 7, line 7 and page 15, lines1-10). Specifically, Corti teaches that the anti-tumor activity was not changed by the addition of human serum albumin to TNF and NGR-TNF solutions, as the carrier (page 15, lines 1-3)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use human serum albumin as the carrier in the kit taught by Terman, Rouslahti et al. and Patierno et al. in view of Corti. One would have been motivated to do so because Corti teaches that the anti-tumor activity of TNF was not changed by the addition of human serum albumin as the carrier. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by using human serum albumin as the carrier for a pharmaceutical composition comprising a NGR peptide and an immunotherapeutic antigen such as galactose-a-1,3-glalactose, one would not change the anti-tumor activity of the pharmaceutical composition.

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF
October 10, 2006